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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,436	02/18/2004	Pramod B. Mahajan	1121D	6402

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EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT PAPER NUMBER

1638

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

10/782,436

Applicant(s)

MAHAJAN, PRAMOD B.

Examiner

Medina A Ibrahim

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-- The MAILING DATE f this communication appears on the cover sheet with the c rrespondence address --
Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's response filed on 11/22/04 in reply to the Office action of 08/25/04 has been entered. Claims 2-4 have been cancelled. Claim 1 has been amended. Therefore, claims 1 and 5 are pending and are under consideration.

This Office action contains NEW GROUNDS OF REJECTIONS and is made non-final. Any inconvenience the delay may have caused Applicant is deeply regretted.

All previous objections and rejections not set forth below have been withdrawn in view of Applicant's amendment to the claims.

Claim Rejections - 35 USC § 112

Claims 1 and 5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to an isolated polypeptide of SEQ ID NO: 4 and a polypeptide having at least 95% sequence identity thereto having RuvB activity.

The specification states that SEQ ID NO: 4 is from maize and that it has RuvB activity involved in homologous recombination. On the paragraph bridging pages 3 and 4 of the specification, Applicant states "RuvB has two NTP binding motifs, known as Walker A and Walker B boxes, as well as other structural motifs common to DNA

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helicases In the absence of metal ions, RuvB exists as a monomer or dimer in solution. However, the functional form of this enzyme is thought to be a hexamer. Two hexameric RuvB units bind to DNA in a symmetrical manner to form a ring, similar to the hexameric However, a RuvAB complex functions much more robustly, and requires less Mg^{+2} . Thus, RuvB participates in one of the rate limiting steps in homologous recombination in all living organisms". The specification also states that expression of a polynucleotide encoded by said polypeptide in a transgenic plant provides the means to modulate the efficiency with which nucleic acids of interest are incorporated into the genomes of a target plant cell. The specification also states that control of these processes has important implications in the creation of novel recombinantly engineered crop plants.

The specification, however, fails to teach how to use the isolated polypeptide of SEQ ID NO: 4 in a plant or the agronomic benefit of the isolated polypeptide. The specification does not provide guidance regarding any use of the isolated polypeptide. The specification merely provides a laundry lists of uses of all proteins in general including use of the in assays for enzyme agonists or antagonists of enzyme function, for use as immunogens or antigens to obtain antibodies, which can be used in assays for expression levels, or for identifying and/or isolating nucleic acids from expression libraries, and for identification of homologous polypeptides from other species, or for purification of polypeptides of the present invention. However, no guidance has been provided with regard to how to use SEQ ID NO: 4 and polypeptides having at least 95% sequence identity thereto.

In addition, a search of the prior art does not indicate that RuvB polypeptides have well-established function in DNA repair process or homologous recombination in plants. The prior art provides limited information regarding biological activity of RuvB polypeptides. The instant specification provides no working examples as to the activity of the claimed polypeptides, and one of ordinary skill in the art would not be able to predict what activity would be possessed by the protein of the instant application based solely because it has the two NTP binding motifs, known as Walker A and Walker B boxes, as well as other structural motifs common to DNA repair proteins. Furthermore, using the instant polypeptides as immunogens is not a specific biological activity, since any protein can be used for this general purpose. Therefore, without knowing the biological activity for the claimed polypeptides, one of ordinary skill in the art would not be able to use them or predict an activity for them, simply because they comprise the two NTP binding motifs, known as Walker A and Walker B boxes, as well as other structural motifs common to DNA repair proteins.

See *Genentech Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997) where the court stated " It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement". The *Genentech* court also held that [w]hile every aspect of a claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention". *Id.* In this case, as in *Genentech*, the specification does not provide the "reasonable detailto enable

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members of the public to understand and carry out the invention".

Therefore, given the lack of guidance in the specification with regarding how to use the claimed polypeptide; the limited information on polypeptides with RuvB activity and their specific biological function; lack of working examples in the specification; and the unpredictability inherent in predicting the biological activity of proteins based on specific conserved regions; and the nature of the invention as discussed above, one skilled in the art would not be able to use the claimed polypeptide without undue trial and error experimentation.

Remarks

Claims 1 and 5 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest the isolated polypeptide of SEQ ID NO: 4 and polypeptides having at least 95% sequence identity thereto

No Claim is allowed.

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Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM. Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (571) 272-0804.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

1/24/05

Mai

Medina A. Ibrahim
MEDINA A. IBRAHIM
PATENT EXAMINER